## 6.0 510(K) SUMMARY (PAGE 1 OF 5)

JUN 30 2014

| | |
|---|---|
| **Submitter's Name and Address:** | ConforMIS, Inc.<br>28 Crosby Drive<br>Bedford, MA 01730 |
| **Establishment Registration Number:** | 3009844603 and 3004153240 |
| **Date of Summary:** | March 31, 2014 |
| **Contact Person:**<br>**Telephone Number:**<br>**Fax Number:** | Amita S. Shah, Sr. Vice President, Regulatory and Quality Affairs<br>(781) 345-9164<br>(781) 345-0147 |
| **Name of the Device:** | ConforMIS iTotal® Posterior Stabilized Knee Replacement System (iTotal PS KRS) |
| **Common Name:** | Posterior Stabilized Total Knee Replacement System |
| **Regulatory Status and Regulation Number:** | Class II<br>21 CFR 888.3560 |
| **Classification Name:** | Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis |
| **Device Classification:** | Product Code:<br>JWH: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.<br><br>OOG: Knee Arthroplasty Implantation System.<br>Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices. Indicated to include guiding alignment, making or establishing cuts, selecting, sizing, attaching, positioning or orienting implant components.<br><br>OIY: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive.<br>This generic type of device includes prosthesis that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component(s) and/or a retropatellar resurfacing component made of ultra-high molecular weight polyethylene plus an additive, such as a-tocopherol. |

## 510(K) SUMMARY (PAGE 2 OF 5)

**Indications for Use:**

The iTotal PS Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

**This implant is intended for cemented use only.**

**Identification of the Legally Marketed Device (Predicate Device):**

ConforMIS iTotal CR Knee Replacement System (ITOTAL CR KRS)
Device Class: II
Product Code: JWH, OOG, OIY
Regulation Number: 21 CFR 888.3560
510(k) Number: K131467 & K131019

DePuy Attune Knee System
Device Class: II
Product Code: JWH, OIY
Regulation Number: 21 CFR 888.3560
510(k) number: K111433

Zimmer Persona Personalized Knee System
Device Class: II
Product Code: JWH
Regulation Number: 21 CFR 888.3560
510(k) number: K113369

## 510(K) SUMMARY (PAGE 3 OF 5)

**Device Description:**

The iTotal Posterior Stabilized Retaining Knee Replacement System (hereafter referred to as the "iTotal PS KRS") is a patient specific tricompartmental faceted, cruciate sacrificing knee replacement system. The iTotal PS KRS is a semi-constrained cemented knee implant which consists of a femoral, tibial and patellar component.

The system is intended to treat patients who are candidates for total knee arthroplasty where the collateral ligaments are intact. Use of the iTotal PS KRS is usually based on surgeon preference, but it may be also used when total knee replacement is indicated and the posterior cruciate ligament is compromised, absent, or surgically excised.

Using patient imaging (CT scan) and a combination of proprietary and off the shelf software, a patient specific implant is designed, that best meets the geometric and anatomic requirements of the specific patient. The femoral component is manufactured from cobalt chromium molybdenum ("CoCrMo") alloy. The tibial component includes a metal tray manufactured from CoCrMo alloy and a polyethylene insert that is manufactured from ultra-high molecular weight polyethylene (UHMWPE). The patellar component is manufactured from either UHMWPE or from a highly cross-linked Vitamin E infused polyethylene (iPoly XE™).

For user convenience, and similar to the predicate (iTotal CR KRS), ancillary orthopedic manual surgical instruments designed for use with the iTotal PS KRS are provided to assist with implantation. The ancillary instruments are provided sterile and for single-use only. These patient specific instruments are provided to assist in the positioning of total knee replacement components intra-operatively and in guiding the cutting of bone.

The intended use and function of the patient specific ancillary instruments remain similar to those described in the predicate 510ks i.e. **K131467 & K131019**. There are only a few differences such as the addition of jigs to guide the bone cutting for the femoral box, the introduction of a full thickness flexion spacer to help assess joint space, and the insert trials that are made to match the tibial insert with the spine feature.

## 510(K) SUMMARY (PAGE 4 OF 5)

**Substantial Equivalence:**

The product subject of this premarket notification is substantially equivalent in design and functionality to the iTotal Cruciate Retaining Knee Replacement System (**K131467**, cleared July 18, 2013 & **K131019**, cleared May 24, 2013); the DePuy Attune PS Total Knee System (**K111433**, cleared August 30, 2011); and the Zimmer Persona PS Personalized Knee System (**K113369**, cleared March 27, 2012).

Functional testing was conducted in compliance with the FDA Guidance *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA*, issued January 16, 2003.

Specifically, the following non-clinical laboratory tests were performed to determine substantial equivalence:

- Femoral Component Fatigue Testing
- Tibial Tray Fatigue Testing
- Tibial Insert Spine-Femoral Cam Fatigue Testing
- Tibiofemoral Contact Area and Surface Stress Testing
- Patellofemoral Contact Area and Surface Stress Testing
- Patellofemoral Lateral Stability Testing
- Tibiofemoral Constraint Analysis
- Rotational Laxity Testing
- Range of Motion Analysis
- Tibial Interlock Strength Testing
- Tibial Insert Push-in/ Push-out Testing
- Cadaveric Evaluation
- Software verification and validation testing
- MR Compatibility Testing

All testing has demonstrated that the device is substantially equivalent to the predicate devices.

## 510(K) SUMMARY (PAGE 5 OF 5)

**Description and Conclusion of Testing:**

**Nonclinical Testing:** The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. Testing on the iTotal PS Knee Replacement System included functional testing in compliance with The FDA Guidance *Class II Special Controls Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA,* issued January 16, 2003.

Specifically, the following non-clinical laboratory tests were performed to determine substantial equivalence:

- Femoral Component Fatigue Testing
- Tibial Tray Fatigue Testing
- Tibial Insert Spine-Femoral Cam Fatigue Testing
- Tibiofemoral Contact Area and Surface Stress Testing
- Patellofemoral Contact Area and Surface Stress Testing
- Patellofemoral Lateral Stability Testing
- Tibiofemoral Constraint Analysis
- Rotational Laxity Testing
- Range of Motion Analysis
- Tibial Interlock Strength Testing
- Tibial Insert Push-in/Push-out Testing
- Cadaveric Evaluation
- Software verification and validation testing
- MR Compatibility Testing

Test results demonstrated that the device is safe and can be considered substantially equivalent to the predicate devices for the intended use.

**Safety and Performance:**

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. The testing demonstrated that the device is safe for its intended use and can be considered substantially equivalent to the predicate devices. Clinical data is not necessary to demonstrate substantial equivalence.

**Conclusion:**

Based on the testing conducted, it is concluded that the iTotal Posterior Stabilized Knee Replacement System is substantially equivalent to the predicate devices: the iTotal Cruciate Retaining Knee Replacement System (**K131467**, cleared July 18, 2013, & K131019, cleared May 24, 2013); the DePuy Attune PS Total Knee System (**K111433**, cleared August 30, 2011); and the Zimmer Persona PS Personalized Knee System (**K113369**, cleared March 27, 2012).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

ConforMIS, Incorporated
Ms. Amita Shah
Senior Vice-President, Regulatory & Quality Affairs
28 Crosby Drive
Bedford, Massachusetts 01730

Re: K140833
Trade/Device Name: ConforMIS iTotal® Posterior Stabilized (PS) Knee Replacement System (iTotal PS KRS)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OOG, OIY
Dated: March 31, 2014
Received: April 2, 2014

Dear Ms. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K140833

**Device Name:**
ConforMIS iTotal Posterior Stabilized (PS) Knee Replacement System (iTotal PS KRS)

**Indications for Use:**

The iTotal PS Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

**This implant is intended for cemented use only.**

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D

Division of Orthopedic Devices